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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/895,975 | 06/29/2001 | Mark R. Schmitt | AM100341 | 9267 |

25291 7590 08/09/2005

WYETH
PATENT LAW GROUP
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EXAMINER

TRUONG, TAMTHOM NGO

| | |
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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,975

Applicant(s)

SCHMITT ET. AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,6-8,10-12,14-20,22,67,74-77,79-81,83-85,87-93 and 95-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,6-8,10-12,14-20,22,67,74-77,79-81,83-85,87-93 and 95-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5-16-05</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Applicant's amendment of 5-16-05 has been fully considered. Claim 67 has been amended to include "cervical" cancer which has support in the specification. Claim 98 is added as a claim dependent on claim 67. No new matter is noted. However, applicant's argument is not found persuasive, and thus, the previous "Scope of Enablement" rejection is maintained.

Claims 1, 5, 9, 13, 21, 23-66, 68-73, 78, 82, 86 and 94 have been cancelled.

Claims 2-4, 6-8, 10-12, 14-20, 22, 67, 74-77, 79-81, 83-85, 87-93, 95-98 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 2-4, 6-89, 10-12, 14-20, 22, 67, 74-77, 79-81, 83-85, 87-93 and 95-97 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of lung cancer, glioblastoma, melanoma, colon and cervical cancers, does not reasonably provide enablement for other types of cancer such as: liver cancer, pancreatic cancer, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 98 is rejected as being dependent on claim 67.

The rejection is maintained for reasons stated previously and for the ones below:

- a. Applicants traversed the rejection by citing different cell lines used in studies presented in the specification. Still, the tests on those cell lines do not cover for the

treatment of cancer in general or as defined in the specification, which includes breast, kidney, bladder, mouth, larynx, esophagus, stomach, ovary, pancreas, liver, etc.

b. Even though a large number of compounds is tested, those compounds have certain fixed substituents. That is, they tend to have R^3 as Cl, R^4 as hydrogen, R^2 is phenyl substituted with fluoride (e.g., difluorophenyl, trifluorophenyl, or trifluoromethyl-phenyl), and R^1 is not as extensively substituted. Another word, the tested compounds appear to belong to a very narrow subgenus, and thus, their activity cannot be extrapolated to the entire genus of formula (I) wherein R^1 , R^3 and R^4 represent all sort of moieties, rings which in turn could be extensively substituted.

c. Applicants further cited references relating anti-tumor agents tested with other cell lines. However, the compounds tested in said references are not analogues or derivatives of triazolopyrimidine. Because of structural differences, the teaching in said references could not be extended to the claimed triazolopyrimidine compounds.

d. An update search yields references (cited on PTO-892) teaching triazolopyrimidine compounds as agents treating cardiovascular diseases, diabetes, atherosclerosis, anemia, or as fungicides used in agriculture. Therefore, the state of the art does not sufficiently guide the skilled oncologist to effectively select a compound from the large number of compounds covered by formula (I) in the treatment of cancers other than lung cancer, colon cancer, cervical cancer, glioblastoma, and melanoma (skin).

e. Regarding claim 75 which recites a method of treating cancerous cells that express multiple drug resistance (MDR), applicants asserted that there is ample of

support for the enablement of said claim and its dependent claims 74, 76, 77, 79-81, 83-85, 87-93 and 95-97. Applicants cited support in Table 4 and Table 5 for data on treating cancerous cells with MDR. However, in said Tables, it seems that a larger dose is still required for the claimed compounds though not as much as Taxol, Vincristine, Doxorubicin, and Mitoxantrone. Still, the activity of the claimed compounds in treating MDR cancerous cells is not any better than Nocodazole. Therefore, it would not be practical to select the claimed compounds for such a treatment since the safety profile has not been established for those compounds. Again, only a limited number of compounds were tested, which is not adequate to cover the scope of the claimed formula (I).

Thus, with the unpredictable nature of oncology and the limited teaching provided by the specification and the art, it would require undue experimentation to treat cancer or MDR cancerous cells as claimed herein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

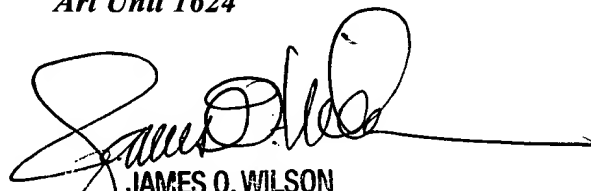
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tamthom N. Truong
Examiner
Art Unit 1624

8-5-05



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SUPERVISORY PATENT EXAMINER
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